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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,962	02/16/2001	Gordon Moore Allan	454313-2338.1	6400

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EXAMINER	
FOLEY, SHANON A	9

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/784,962	ALLAN ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-67* is/are pending in the application.

4a) Of the above claim(s) *41 and 55-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-40,42-54 and 65-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 February 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/347,594* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that differences between methods of making do not qualify under MPEP § § 806.04 and 808.01. Applicant also states that the claims are drawn to vaccine compositions and not inactivated/attenuated whole antigens, subunit antigens or vectors. Applicant also asserts that the since all of the interrelated groups are classified under 424, an undue burden of search has not been demonstrated.

Applicant's arguments have been carefully considered, but are found unpersuasive. Although there is discussion in the Office action for different methods of making the different compositions, the Office action also states that these compositions are structurally and functionally divergent, see the last paragraph on page 2. This functional divergence between the compositions is readily apparent from the nature of each component. Attenuated and inactivated viruses contain the natural components of a virus, which are presented to the immune system in the form that would be presented by a wild-type virus. DNA and live vectors carry foreign genes, which structurally distinguishes them from attenuated or inactivated viruses. When these vectors are administered, the expression of the heterologous gene elicits a distinctly different immune response from attenuated or inactivated viruses. Finally, subunit antigens are proteins, which are structurally distinguished from inactivated/attenuated viruses or vectors by their amino acid residue structure. Subunit antigens functionally differ from attenuated/inactivated viruses or vectors because they are incapable of infection or expressing heterologous genes. Therefore, it is

maintained that the various vaccine compositions claimed are have different modes of operation, different functions and have different effects on the immune system. Although the claims are drawn to vaccine compositions, the components of the vaccine are patentably distinct due to their structural and functionally divergent nature. This satisfies the first criterion for a proper restriction requirement according to MPEP § 803.

The second criterion required by MPEP § 803 is burden of search, which has also been demonstrated by the Office. The various components recited in groups I, II, or III require non-overlapping, separate fields of search, as evidenced by their separate classification in the art. Although the groups are classified in the same class, the groups are not classified in the same subclass. As discussed in the Office action, a search for attenuated/inactivated viruses does not overlap with structurally and functionally different vectors expressing heterologous inserts or subunit antigens. Conversely, a search for vectors does not preclude a search for attenuated/inactivated viruses or subunits. Finally, a search for antigenic subunits, which have no structural characteristic in common with viruses or vectors, would not overlap with a search for viruses or vectors.

In conclusion, the restriction requirement satisfies all of the criteria set forth in MPEP § 803 is still deemed proper and is therefore made FINAL.

Claims 41 and 55-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8. Claims 38-40, 42-54 and 65-67 are under consideration.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Although the first line contains a reference to FR application number 98 0877, there is no mention of 09/347,594 found in the oath.

Drawings

The drawings are objected to because It appears that Figure 5b is absent from the disclosure because Figures 5a, 5c and 5d are present. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Applicant is reminded that no new matter may be introduced into the specification.

Specification

The disclosure is objected to because of the following informalities: there are two completely different abstracts present in the disclosure. The first is on page 37 and relates to the

invention and the second is present on the next page which details inducing an immunological response in an avian host.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 42 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent that the specific circovirus type II strains listed are required to practice the claimed invention because they are recited elements in the claim. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of porcine circovirus type II strains listed in the claim. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the porcine circovirus type II strains listed in the claim and it is not apparent if it is readily available to the public. Applicant's deposit statement in the specification bridging pages 2 and 3 does not indicate the extent of public availability. The MPEP § 2404.01 states that: "A mere reference to a deposit of biological material itself does not necessarily mean that the biological material is readily available." If the deposit is made under the terms of the Budapest Treaty, then an

affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

Claims 38-40, 42-54 and 65-67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protecting against porcine parvovirus infection and inducing an immune response in a porcine subject against porcine circovirus, does not reasonably provide enablement for a vaccine to treat and prevent porcine circovirus infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

To comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, the specification must enable one skilled in the art to make and use the claimed invention without undue experimentation. The claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the

claims. Such an analysis does not need to specifically enumerate (points 1-8) but only needs to have a select few of the factors present discussed in a rejection.

The breadth of the claims comprise a vaccine comprising at least one inactivated or attenuated parvovirus antigen and at least one inactivated or attenuated circovirus antigen, more narrowly derived from type II, and a veterinarily acceptable excipient. This formulation also comprises additional antigens of other porcine pathogens, as well as an adjuvant and stabilizer. The nature of the invention is drawn to a vaccine against porcine multisystemic wasting syndrome (PMWS). The nature of the invention is evidenced throughout the specification, see page 1, lines 1-4 for example.

A vaccine is defined as a composition comprising live or attenuated microorganisms that stimulate specific T cell immunity as well as neutralizing antibodies. The definition also states that a vaccine should be effective and well tolerated, see the definition provided for "vaccine" by Cruse et al. (The Illustrated Dictionary of Immunology, 2nd ed. Boca Raton: CRC Press; 2003: 613).

The state of the prior art for a vaccine against porcine parvovirus (PPV) is well developed in the art, see Young. Parvoviruses. *In* B.N. Fields et al. (ed.), Fields Virology, 3rd ed. Philadelphia: Lippencott-Raven Publishers; 1996: 2213. However, the state of the art for a porcine circovirus (PCV) and PMWS vaccine is much less developed. Krakowka et al. (Viral Immunology. 2002; 15 (4): 567-582) teach that clinical induction of PCV-2 results in two distinct disease syndromes, PMWS and porcine dermatitis and nephropathy syndrome (PDNS). Krakowka et al. also teach that although PMWS symptoms have been artificially stimulated in piglets by co-inoculation of PCV-2 and another immune stimulant, such as PPV, PRRS or an oil-

based emulsified immunogen, PDNS has not been reproduced, see the abstract and the first full paragraph on page 578. While manifestation of PMWS lesions were reduced upon administration of cyclosporine (Cys), the amount of PCV-2 virus produced is augmented. Krakowka et al. discuss the clinical ramifications of high titers PCV-2 viral titers and the host's immune system, see the results and discussion sections. There is no teaching in the prior art or the disclosure that suggests that administration of an attenuated or inactivated PCV-2 virus would induce specific T cell immunity as well as neutralizing antibodies against PMWS and PCV that would be well tolerated by a host.

The level of predictability to one of ordinary skill in the art for vaccine development is low even with known causative agents. One of skill in the art would have doubt the instant vaccine's effectiveness and may even conclude that the claimed composition may cause detrimental effects if administered as a vaccine due to the lack of guidance provided in the disclosure. The specification provides evidence that piglets injected with PCV and PPV develop PMWS symptoms in examples 20 and 21, but there is no evidence in the examples of treating or preventing PMWS or PCV infection.

Considering the scope of the claims, the nature of PMWS infection, the undeveloped state of the art for circovirus treatments and vaccines, the unpredictability of protective or therapeutic immune responses, the lack of guidance provided in the specification remedying the deficiencies and doubts in the art, and the lack of working examples drawn to treating an preventing PCV-2 infection or PMWS with the instant compositions, it is concluded that an undue experimentation would be required to make or use the claimed invention commensurate with the scope of the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38-40, 42-54 and 65-67 (to the extent that these claims encompass immunogenic compositions) are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 22 and 24-30 of U.S. Patent No. 6,217,883. Although the conflicting claims are not identical, they are not patentably distinct from each other because the components within the compositions and the method of inducing are the same, i.e. inactivated and/or attenuated parvovirus and circoviruses.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
March 19, 2003

JAMES HOUSEL 3/23/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600